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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/357,423 | 07/20/1999 | THOMAS M. BAER | 17726-726 | 9233 |

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EXAMINER

CROSS, LATOYA I

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1743

DATE MAILED: 06/28/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

MF-13

Office Action Summary

Application No.

09/357,423

Applicant(s)

BAER, THOMAS M.

Examiner

LaToya I. Cross

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 5-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 25-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 8, 2002 has been entered. Claims 1-37 are pending. Claims 5-24 are withdrawn from consideration as being directed to non-elected subject matter.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,741,710 to Ek.

Ek teaches a reaction vessel for processing sample and quantitatively assaying components in the sample. The reaction vessel contains a reaction chamber (11) having a port (12) at one end. The port is in fluidic contact (in fluidic connection) with a sample carrier tube (25). See figure 1 and col. 2, line 60 – col. 3, line 17. At col. 4, lines 51-55, Ek teaches that the reaction chamber may also operate in extraction of components in the sample.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b), in view of the teachings of Ek '710.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 4, 26, 28, 29 and 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,084,660 to Shartle (hereinafter Shartle '660).

Shartle '660 discloses a device for measuring an analyte concentration of a blood sample. The device has a sample port (12), a channel (16), a measurement area (18), and a stop junction (22) (col. 5, lines 3-11). The sample port serves as a sample carrier and sample application area for introducing sample into the device. The sample port is also attached to layer 28, which provides a surface to which sample is applied. See figure 4. Channel (16) has a first end and a second end. The first end connects to the sample port. The second end connects to the measurement area (18). The channel provides a fluidic path between the sample port and measurement area. The measurement area provides a location for reagents to react with the sample and undergo changes providing an optical parameter for measuring the amount of analyte in the sample. The stop junction (22) provides a means for stopping flow of sample into the measurement area after it is filled. The device may be in the form of a laminate layered to form each of the chambers as shown in figure 2. In figures 7 and 8, Shartle '660 shows several different chambers having ports and conduits connected to each chamber and providing a fluid flow between the chambers.

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Shartle '660 differs from the instant invention in that 1) the reference does not specifically disclose a reaction chamber and 2) there is no specific disclosure of a pump.

With respect to the reaction chamber, as recited in claims 1 and 4, Shartle '660 discloses that the measurement area contains a reagent (20) and that the sample undergoes a change when in contact with the reagent in the measurement area (col. 5, lines 14-21 and col. 6, lines 10-12). Therefore, it would have been obvious to one of ordinary skill in the art that the measurement area would serve as the reaction area also.

With respect to the pump as a part of the device, Shartle '660 discloses a bladder member (14). The bladder is compressed and creates a suction force to draw the sample into the device. It is the position of the Examiner that the bladder in Shartle '660 serves as a pump mechanism, absent evidence to the contrary.

Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the disclosure of Shartle '660.

6. Claims 3, 25, 27 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shartle '660 as applied to claims 1, 4, 26, 28, 29 and 31-37 above, and further in view of US Patent 5,627,041 to Shartle (hereinafter Shartle '041).

Shartle '660 fails to disclose a dilution chamber in the device. Shartle '660 also fails to disclose the sample processing device as a centrifuge tube.

Shartle '041 discloses a laminated sample analyzing device similar to the device described in Shartle '660. The sample analyzing device contained several layers of material formed into chambers, reservoirs and channels. The device has a sample chamber, mixing chamber, reagent chamber, and dilution chamber. Shartle '041 teaches that the dilution

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chamber is necessary to dilute biological sample in order to accurately detect the amount of target analyte in a sample (col. 2, lines 11-20). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate a dilution chamber into the device of Shartle '660 to allow more accurate measurement of the analyte content in the sample.

Regarding the processing device being a centrifuge tube, Shartle '041 discloses incorporating the laminated analytical instrument into a centrifuge cartridge to allow fixed volume assays to move fluids throughout the device. It would have been obvious to one of ordinary skill in the art to incorporate the laminate structure of Shartle '660 into a centrifuge device to help move the sample around the device and allow the sample to contact the reagents and provide the user with a quantitative measurement of the concentration of analyte in the sample.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teachings of Shartle '660 and Shartle '041.

Response to Arguments

7. Applicant's arguments filed April 8, 2002 have been fully considered but they are not persuasive. Applicants argue, with respect to the rejection over Ek, that the claims now recite a biological sample being coupled to the surface of the sample carrier. Essentially, Applicants are attempting to claim the sample that the device uses. MPEP 2115, materials worked upon do not impart patentability to the claimed invention. Furthermore, Applicants use the phrase "coupled to", which given the plain meaning means "linked to" or "connected to". Applicants admit in their arguments that Ek teaches the sampled being connected via tubes and valves to the reaction chamber. Thus, the sample port is coupled with the reaction chamber.

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With respect to the rejection over Shartle, Applicants argue that the reference does not teach a sample carrier, a sample carrier mated to a reaction chamber and a sample carrier having biological sample coupled to the surface of the sample carrier. The Examiner disagrees. Shartle clearly teaches sample port in contact with a layer (28) where sample is introduced into the port and contacts the bottom layer. A channel (16) connects the sample port with a measurement zone where reactions occur. The channel allows fluid communication between the sample port and the measurement zone.

Applicants argue the presence of multiple port, however, Shartle '660 teaches several chambers forming ports and conduits in figures 7 and 8. Applicants also argue the presence of centrifuge tube, which is also taught by Shartle '041.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC

June 24, 2002


Jill Warden
Supervisory Patent Examiner
Technology Center 1700